**PT. SINKO PRIMA ALLOY**

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|---|---|
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**CONTENT**

# 1 Overview

## 1.1 Purpose

This product is intended to be used in conjunction with the syringe to control the dose of liquid infused into the patient's body in clinical departments.

## 1.2 Contraindication

None.

## 1.3 Product Features

Medical Syringe Pump is a micro-volume continuous-operation syringe pump. It ensures constant infusion rate and accurate dosing volume during prolonged infusion. This syringe pump is used for continuous and micro-volume infusion of liquid or liquid medicine of little volume and high concentration, for example, infusion of chemotherapeutic agents, cardiovascular drugs, antineoplastic, oxytocic, anticoagulant, anesthetic agents, etc.

- All current disposable syringes conforming to the IEC standard for medical disposables are supported.
- Disposable syringes of 5ml, 10ml, 20ml, 30ml, and 50/60ml can be automatically identified.
- Eleven occlusion levels are available, and the pressure status of the tube is displayed.
- Large rate range (up to 2000ml/h for 50/60ml syringe).
- Calibration functions are provided for infusion accuracy.
- Safety design by monitoring infusion status of syringe.

- Multiple infusion modes.
- The infusion rate can be changed during infusion.
- Power-on self-test, including power supply, circuit, motors and sensors.
- WIFI function, supporting connection to the central monitoring system.
- Support wired communication with the central monitoring system through LAN.
- Nurse call function.
- Touchscreen, providing quick and convenient man-machine interface.
- Display night mode, reducing light interference to patients and environment.
- Double/quadruple CPU, and redundancy design for key units, which will protect the patient from over-infusion and under-infusion.
- Three types of power supply are supported: AC power supply, DC power supply, and internal lithium battery.
- Two-way alarm for monitoring the main control circuit and motor drive circuit.
- Independent motor driving CPU and motor subdivided drive chip design, which will protect the patient from over-infusion and under-infusion.
- Setting of maintenance interval and automatic prompt of maintenance.
- Meet the requirement of EN1789 standard. Can be used in the road

ambulances environment.

Note:

WIFI communication module, LAN communication module, nurse call and relay infusion functions are optional features.

## 2 Precautions for Use

In this manual, precautions are classified into warning and caution paragraphs according to their importance. The meanings are as follows:

 WARNING:

The information is about safety and efficiency. Operation against the precautions may cause injuries.

 CAUTION:

The information is about guiding suggestions. Operation against the precautions may affect normal use of the product. Read carefully the warnings and cautions in this manual.

 WARNING:

- The syringe pump must be operated by trained healthcare professionals.
- Prior to use, please check the status of the pump, power cable and other related accessories to ensure that the device can be used normally and safely.
- The syringe pump does not support air-in-line detection. Always purge air from the system before each use.
- Pay extra attention to twists of the infusion line when it is used for low-rate infusions. A lower infusion rate indicates a longer time from

occurrence to detection of the occlusion, which may suspend the infusion for a long time.

- To avoid the risk of fire or explosion, do not use the syringe pump in a flammable or oxygenated environment.
- The altitude difference between the pump and heart position of the patient should not be larger than 100cm. A smaller altitude difference indicates a higher accuracy of the pressure sensor's result.
- In the event of tube twisting, filter condensation or tube occlusion during infusion, the internal pressure of the infusion tube increases. When the occlusion alarm is generated, the motor automatically rotates inversely to release the pressure in the tube (Anti-Bolus function), so that no extra bolus will be infused during the operation of clearing the occlusion alarm.
- It is recommended that you use the syringes specified by the manufacturer only.
- If a syringe of other brands is used or the syringe parameters are not defined correctly, the infusion accuracy may be affected.
- Only the syringe, tube, syringe needle and other medical parts complying with local regulations can be used on the syringe pump. Contact your local distributor for more information.
- Operating the syringe pump against the requirements, procedures, warnings or cautions provided in this manual may cause infusion failure, inadequate or excessive dosing, and/or other potential risks.
- There should be regular monitoring by trained healthcare professionals during use of the device.
- The power cable and other affiliated lines should be laid properly to

prevent patients from being tripped and avoid electromagnetic interference.

- Electric equipment like high-frequency electric knife and mobile phone may have electromagnetic interference on the syringe pump.
- To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earthing.
- If the pump and its related accessories reach the end of their economic life time, they must be scrapped and disposed of in accordance with local laws or hospital regulations. Please contact your local representative for further details.
- Do not replace any component of this equipment without authorization of the manufacturer.
- When operating the pump or checking the pump's alarm systems, the operator should be in front of the device, no farther than 1 meter away.
- There is no patient circuit in this device. The output of the equipment is not allowed to be accessible to a patient.
- The operator shall not touch the pump and a patient simultaneously.
- Before using the pump, please double check the parameters on the appropriate screen before starting the infusion.
- To prevent infusion rate changes and infusing air into the patient's body, make sure no other infusion systems or accessories are connected to the patient line simultaneously.

CAUTION:

- The applied part of the syringe pump is the infusion catheter and infusion tube.

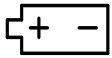
- Infusion can be started only when the prescribed values on the prescription are the same as the values set on the syringe pump.
- Ensure that the syringe pump is fixed tightly on the stand and the stand is stable, or securely placed on a flat platform.
- Prevent the pump from colliding, dropping, mechanical vibration and other external forces to avoid damage to the pump.
- Before tapping the [Start] button, check if the infusion rate is correct, especially the position of the decimal point.
- Do not operate on the screen with sharp objects. Otherwise, the screen may be damaged.
- An occlusion alarm may be generated when high-viscosity liquid is infused at high rate through a thin intravenous needle. In this case, increase the occlusion level or decrease the infusion rate.
- Syringe pump should be placed without the reach of patients and unauthorized healthcare personnel.
- Avoid direct sunlight, high temperatures and high humidity.
- Do not autoclave the syringe pump.
- Before operating the pump powered by its built-in battery, check the battery to ensure that sufficient power is available. Recharge the battery if required.
- Ensure that a battery is installed in the syringe pump before operation. Otherwise, the system may stop working without reporting an alarm when external power is interrupted due to power failure or a short circuit, causing an unsafe condition.
- If the syringe pump cannot work as described in this manual for unknown

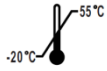
reasons, stop it and report the details (including syringe model, infusion flow, serial number of syringe pump, and type of infusion liquid) to your local distributor or PT. SINKO PRIMA ALLOY customer service department.

- Do not disassemble or reconstruct the syringe pump.
- Liquid intrusion into the AC power socket, USB or nurse call socket may cause short circuit. While connecting the power cable, check if the connecting parts are dry. If liquid spills onto the syringe pump, clean the pump with a dry cloth, and use the pump after inspection by maintenance personnel.
- The maximum temperature at the applied part of the pump may reach 42.2°C when the pump runs continuously under the highest environment temperate at the highest infusion rate.
- The highest pressure at the end of the infusion tube is not higher than 1900 mmHg in case of occlusion.
- The delay inherent in the determination of an ALARM CONDITION is about 100ms.
- The mean delay time from the onset of the ALARM CONDITION to the point that the representation of the ALARM CONDITION leaves the SIGNAL INPUT/OUTPUT PART is about 3.1s.
- After the pump is exposed to a defibrillation voltage, the recovery time of the pump is shorter than 1s (the pump functions properly during exposure to the defibrillation voltage).

**SYMBOLS:**

| | |
|---|---|
| EC REP | Authorized Representative in the European Community |

| | |
|---|---|
| CE 0123 | CE Mark: conforms to essential requirements of the Medical Device Directive 93/42/EEC. |
|  | Manufacturing date |
|  | Manufacturer |
| SN | Serial number |
|  | Defibrillation-proof type CF applied part |
|  | Alternating current |
|  | Direct current |
|  | Alternating current or Direct current |
|  | Battery |
|  | DISPOSAL: Do not dispose this product as unsorted municipal waste. Separate collection of such waste for special treatment is necessary. |
|  | CAUTION! Read the accompanying document. |
|  | General warning sign |
|  | Refer to the operation manual. |
| IP34 | Protected against solid foreign objects of 2.5 mm Ø and greater, Protected against splashing water. |
|  | Interferences may occur near devices with the below sign. |
|   | ON/OFF |
|   | HOME |
|  | Nurse call |

| | |
|---|---|
|  | Protective earth. |
|  | USB interface. |
|  | This way up |
|  | Fragile, handle with care |
|  | Keep dry |
|  | Keep away from sunlight |
|  | Atmospheric pressure limitation |
|  | Temperature limit |
|  | Humidity limitation |
|  | Stacking limit by number<br>(n is 5, 7…, for the specific value, see the product package box.) |

## 3. Product Specifications

| | |
|---|---|
| Product name | Syringe pump/Dual-channel syringe pump |
| Model | MSP-01 |
| Power supply | AC power supply:<br>MSP-01: AC 100-240V,50/60 Hz, 40 VA input power |
| | Built-in battery: lithium battery<br>Battery model: 18650-3S1P-02 2600mAh @10.8V<br>Battery charging time:<br>Power on: Less than 10 hours to full<br>Power off: Less than 5hours to full |

| | |
|---|---|
| Battery operation time | Not less than 10 hours<br>Note: Infusion at 5 ml/h with new battery under room temperature |
| Compatible syringes | All syringes of 5ml, 10ml, 20ml, 30ml, and 50/60ml conform to the standard. |
| Infusion mode | Rate mode, Time mode, Weight mode, Sequence mode,<br>Loading Dose mode, Trapezia mode, Micro mode, TIVA mode |
| Infusion setting range | 0.10-100.0ml/h (5ml syringe)<br>0.10-300.0ml/h (10ml syringe)<br>0.10-600.0ml/h (20ml syringe)<br>0.10-900.0ml/h (30ml syringe)<br>0.10-2000ml/h (50/60ml syringe)<br>See the least increment in chart 6-3 |
| VTBI setting range | 0.10 - 99.99ml (Least increment 0.01)<br>100.0 - 999.9ml (Least increment 0.1)<br>1000 - 9999ml(Least increment 1) |
| Total volume display | 0-9999.99ml |
| Accuracy | Mechanical accuracy: ±0.5%<br>Accuracy (connected to a syringe): ±2% |
| KVO rate | 0.1~5ml/h. KVO can be disabled when KVO rate is set to 0 ml/h.<br>KVO cannot be started if the KVO rate is set to a value greater than the infusion rate. |
| Occlusion level | 225mmHg~975mmHg, 11 levels are available. Occlusion alarm accuracy of the syringe pump ±145mmHg. |

| | |
|---|---|
| Purge operation | 100.0ml/h (5ml syringe)<br>300.0ml/h (10ml syringe)<br>600.0ml/h (20ml syringe)<br>900.0ml/h (30ml syringe)<br>2000ml/h (50/60ml syringe) |
| Bolus operation | 0.10-100.0ml/h (5ml syringe)<br>0.10-300.0ml/h (10ml syringe)<br>0.10-600.0ml/h (20ml syringe)<br>0.10-900.0ml/h (30ml syringe)<br>0.10-2000ml/h (50/60ml syringe)<br>Automatically calculate the bolus rate by bolus amount, cannot be lower than the current rate. |
| Bolus VTBI | 0.10-5.00ml (5ml syringe)<br>0.10-10.00ml (10ml syringe)<br>0.10-20.00ml (20ml syringe)<br>0.10-30.00ml (30ml syringe)<br>0.10-50.00ml (50ml/60ml syringe) |
| Time | 00:00:01-99:59:59 (minimum increment: 1s) |
| Alarm | Near Finished, Finished, Syringe Empty, Syringe Near Empty, OCCL, Pressure Alarm, Low Battery, Battery Empty, No Battery, No Power Supply, Syringe Unknown, Syringe Install Error, Standby End, Reminder Alarm, Tube Off(only 30, 50/60 ml syringe) |

| | |
|---|---|
| Special function | Repeat alarming: After the sound of an alarm is muted, this alarm is reported again two minutes later if it persists.<br>Event recording: A maximum of 2000 events can be stored for playback.<br>Sound volume:10 levels are available<br>Power supply switching: When AC/DC power supply is cut off, the infusion pump automatically switches to built-in battery supply.<br>Barcode scanning: Input the patient information by barcode scanning (optional) |
| WIFI function (optional) | Connect to the central monitoring system, nurse pager, and infusion information network. |
| LAN function | LAN function: Use LAN module to connect the central monitoring system. |
| Drug Library | A maximum of 2,000 drug types can be stored. |
| Operating conditions | Temperature: 5°C to 40°C<br>Humidity:15% to 95% RH, non-condensing<br>Pressure altitude: 57.0kPa-106.0kPa |
| Operating Altitude | Not higher than 5000m |
| Storage and Shipping conditions | Temperature: -20°C to +55°C<br>Humidity: 10% to 95% RH, non-condensing<br>Pressure altitude:22.0kPa-107.4kPa |
| Classification | 1. Class I/Internally powered equipment;<br>2. Defibrillation-proof type CF applied part;<br>3. IP34;<br>4. No sterilization requirement for pump<br>5. Not category AP/APG equipment;<br>6. Mode of operation: continuous |
| Dimensions | MSP-01: 362 x 126 x 151 mm (L x W x H) |
| Weight | MSP-01:About 1.8 kg (standard configuration) |

| | |
|---|---|
| Service Life | 10 years |
| Main safety standards | IEC60601-1 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance<br>IEC60601-2-24 Medical electrical equipment-Part 2-24: Particular requirements for the safety of infusion pumps and controllers<br>IEC60601-1-8 Medical electrical equipment-Part 1-8: General requirements for basic safety and essential performance -- Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems<br><br>IEC60601-1-2 Medical electrical equipment-Part 1-2: General requirements for basic safety - Collateral standard: Electromagnetic compatibility requirements and tests<br>EN 1789:2007+A2:2014(E) Medical vehicles and their equipment — Road ambulances |

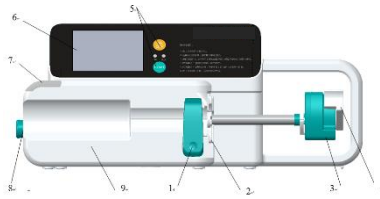


# 4 Product Description

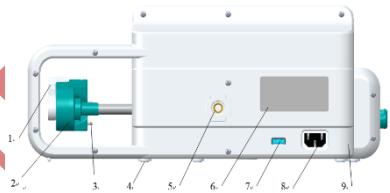
## 4.1 Operating Principle

The MSP-01 syringe pump mainly consists of the pump shell, display and operating system, monitoring system, alarm system, motor drive system, drive module, power supply system, WIFI communication module (optional), LAN communication module, and pole clamp (optional). The MSP-01 syringe pump adopts a dual-processor structure, controls the motor precisely, drives the peristaltic sheet to infuse through the mechanical drive device, monitors the sensors and infusion process, and provides sound-light alarm signal.

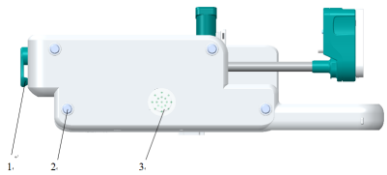
## 4.2 Composition of Syringe Pump MSP-01



1 - Clamp
2 - Syringe fixation
3 - Slider
4 - Clutch
5 - Operation button
6 - Touchscreen
7 - Alarm indicator
8 – Tube clamp
9 - Front housing



1 - Clutch
2 - Slider
3 - Syringe clamp
4 - Floor mat
5 - Threaded hole
6 - Label
7 - External inlet
8 - AC power inlet
9 - Back housing



1 -Tube clamp 2 - Floor mat

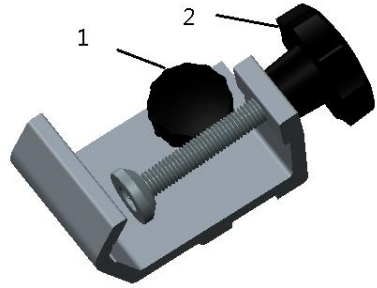
3 - Buzzer

CAUTION:

- Additional equipment connected to medical electrical equipment through the network/data coupling (USB or LAN port) must comply with the respective IEC or ISO standards (e.g. IEC 60950 and IEC 62368-1 for data processing equipment). In addition, all configurations shall comply with the requirements for medical electrical systems (see clause 16 of the 3Ed. of IEC 60601-1, respectively).
- Do not insert accessories not specified by the manufacturer into the external inlets.
- Anybody connecting additional equipment to medical electrical equipment configurations a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your local representative or the technical service department.
- The plug is used as disconnect device to the mains supply, do not to position the pump so that it is difficult to operate the disconnection device.

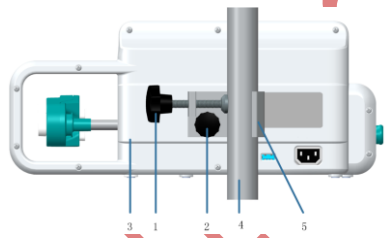


## 4.3 Pole Clamp




1 - Mounting screw

2 - Mounting knob of infusion stand




1 - Mounting knob of infusion stand

2 - Mounting screw

3 - MSP-01 pump

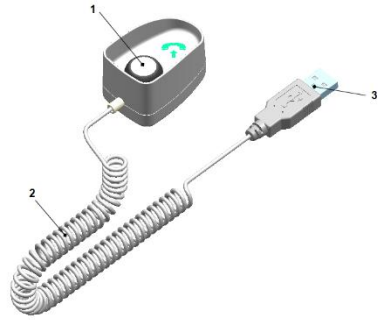
4 - Drip stand

5 - Pole Clamp

Installation method depicted above:

1. Affix the mounting screw (2) into the threaded hole in the back of MSP-01 pump.
2. Hold the handle, and affix the pump to the drip stand (4) by tightening the mounting knob of infusion stand (1).

**4.4** Nurse Call




1 - Button 2 - Cable 3 - Socket

## 4.5 Accompanying Accessories

1 - AC power cable x 1 2 - Pole clamp x 1

3 - Operation manual x 1 4 - Quick operation guide x 1

5 - Packing list x 1

## 4.6 Optional Accessories

Table 4-1 List of Optional Accessories

| Options | Description |
|---|---|
| Power cable | Standard configuration by factory |
| Lithium battery pack | 10.8V@2600mAh |
| Nurse pager | MP-2 |
| Pole clamp | — |
| LAN Module | LAN Communication Module |
| DC power cable | — |

# 5 Preparations for Use

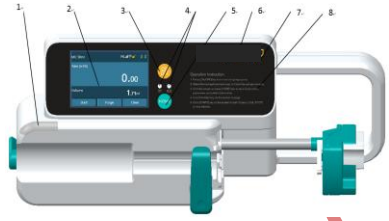
- Before using the syringe pump, read the operation procedures and precautions in this manual carefully.

- Before using the syringe pump for the first time, set the date and time to ensure that the pump history will be recorded correctly.
- Before using the syringe pump for the first time, select the brand of the syringe.
- Before using the syringe pump for the first time, recharge the built-in battery fully. If the syringe pump is off, the battery should be charged fully after being connected to an external power supply.
- Place the syringe pump on a stable platform.
- Alternatively, use the provided pole clamp to mount the syringe pump on an infusion stand.
  - Put the syringe pump on the pole clamp while aligning the retaining knob with the threaded hole, and rotate the handle to fix the syringe pump on the pole clamp.
  - Clamp the pole clamp on the infusion stand, adjust the syringe pump to an appropriate position, and tighten the retaining knob for infusion stand on the pole clamp.
- Connect external power supply.
  - Insert the supplied AC power cable into the AC inlet on the back side of the syringe pump. Plug the cable into an AC power outlet with grounding terminal.
  - To power the syringe pump with external DC power supply, contact your local distributor for help.

# 6 Operating Instructions

## 6.1 Display and Buttons

Display of MSP-01



1 - Alarm indicator
2 - TFT touchscreen
3 - ON/OFF button
4 - Indicator
5 - Home button
6 - Logo
7 - Product model
8 - Operation instruction

The alarm indicator indicates alarms in two colors: red and yellow. This indicator indicates the alarm severity (high, medium, or low) by using different blinking methods. Green light indicates a correct function.

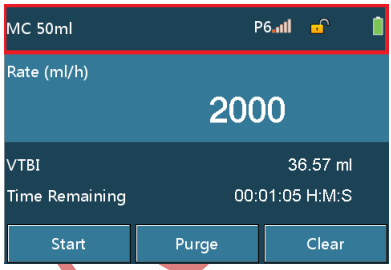
TFT touchscreen, resolution: 480*320

Indicator: The AC/DC indicator on the left, the battery indicator on the right.

- AC/DC indicator: Used to indicate the AC or DC power status. This indicator is steady green when the device is connected to an AC or DC power supply.
- Battery indicator: Used to indicate the battery status. The battery indicator is steady green when the battery is being charged and blinking green when the battery is powering the device. Otherwise,

the battery indicator is extinguished.

The display is divided into three areas: information area, work data area and function button area. See below for further description and explanation.




Information area: Displays the syringe brand and specifications, occlusion pressure level, real-time pressure, external power supply, battery volume, and WIFI signal. Touch the brand and specifications zone to enter the page for syringe brand adjustment. Touch the occlusion pressure level to enter the page for occlusion level selection.

See below for further description.

P2 Occlusion pressure level: 2

Real-time occlusion pressure. Five bars in total. A large number of illuminated bars indicates a higher pressure.

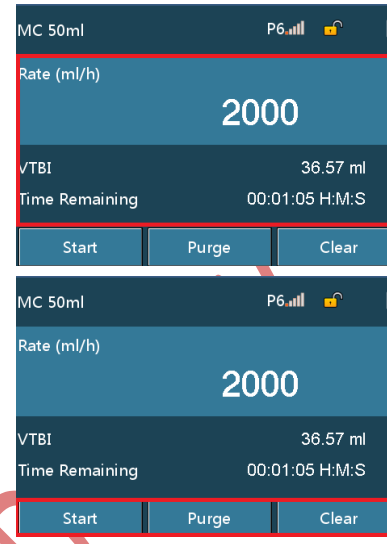
External power source symbol. This symbol is displayed when the pump is connected to an external AC/DC power source.

Screen lock symbol. Two states exist: lock and unlock.

Battery volume and charging status. Four bars in total. A large number of illuminated bars indicates a higher remaining capacity.

WIFI signal

Work data area: Displays the current infusion rate, and infusion volume or displays different infusion work data based on different infusion modes. The work data can be adjusted by touching the specific zone in different working modes.




Function button area: Displays such buttons as [Start], [Purge], [Clear], [Stop], and [Bolus]. Setting buttons such as numbers and letters appear on corresponding interfaces.

- Buttons

In addition to touchscreen buttons, two buttons are available on the button panel: [HOME] and [ON/OFF].

- [HOME]: Main menu button. Before infusion, press [HOME] once to enter a setting menu, such as Infusion set, System Set, History, Patient File, etc. To return to the infusion preparation screen, press [HOME] once again on any setting interface.
- [ON/OFF]: Button for switching on/off the pump. When the pump is off, press [ON/OFF] to switch it on. When the pump is on, press [ON/OFF] and tap the shutdown button on the display to shut down the pump or press and hold [ON/OFF] for 3 seconds to shutdown the pump forcibly.

## 6.2 Powering On the Pump

⚠ CAUTION:

- Power on the pump and then install the syringe.
  - Press [ON/OFF] to switch it on.
  - The self-test starts.
  - After self-test finishes, the infusion preparation screen is displayed.
  - The screen displays patient information, syringe brand and occlusion level stored last time when the device is powered off.
  - If the self-test is abnormal, corresponding information is displayed in the information area.

- Infusion preparation screen:

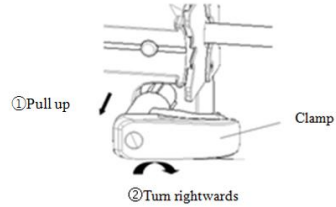

⚠ WARNING

- After the pump is powered on, confirm that the loudspeaker and alarm indicator work properly. Check after the self-test is finished that no error messages appear. (Refer to Chapter 8 Troubleshooting.)
- Confirm that the syringe brand displayed is consistent with the brand of the syringe actually used.

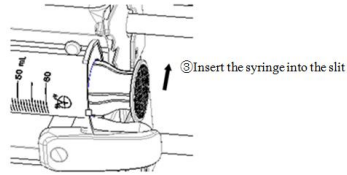
- If the syringe brand set differs from the brand of the syringe actually used, the infusion accuracy and alarm function cannot be guaranteed.
- The total volume is cleared when the [Clear] button is tapped.

## 6.3 Syringe Installation

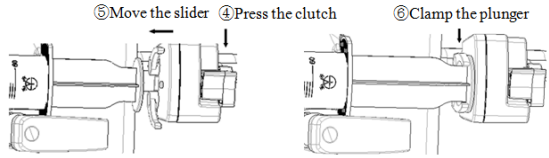
- Pull the clamp and turn it rightwards (①/②)



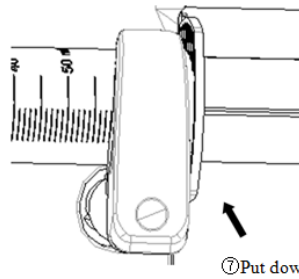

- Press the clutch and move the slider fully to the right.
- Attach the syringe. Insert the flange of the syringe into the slit (③)




- Press the clutch, and move the slider until the contact pin of the slider hits the syringe plunger. (④/⑤/⑥)



- Turn back the clamp and lower it slowly to hold the syringe securely (⑦).



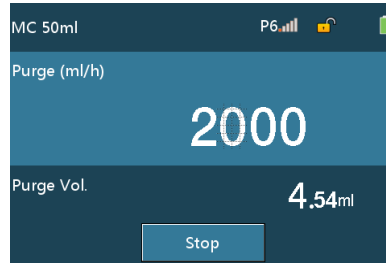

WARNING

- Ensure that no air bubble exists in the syringe.
- If the syringe flange is not properly installed in the slit, flow rate accuracy and alarm function cannot be guaranteed.

## 6.4 Purging

WARNING:

- After installing a syringe on the syringe pump, remove the air bubbles from the syringe IV line.
- Before purging the IV line, ensure that the IV line is not connected to a patient.
- Purging can be done only in non-infusion condition.
- Stop purging after ensuring that liquid is drained out from the needle.




- Tap [PURGE], the purge interface pops up. Tap [Stop], the purging stops.
- The green indicator flashes during purging.
- The purging rate varies with the syringe size. Refer to Table 6-1.

Table 6-1 Relationship between syringe size and purging rate

| Syringe size | Purging rate (ml/h) |
|---|---|
| 5 | 100.0 |
| 10 | 300.0 |
| 20 | 600.0 |
| 30 | 900.0 |
| 50/60 | 2000 |

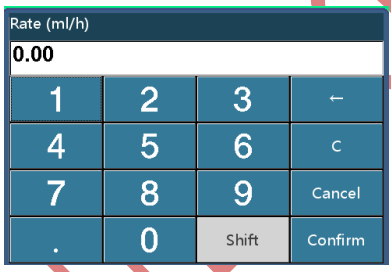
⚠ CAUTION:

- When high viscosity IV fluids are infused through a thin vein needle for purging, an occlusion alarm may be generated. In this case, please reduce the infusion rate manually.
- The volume used for purging will be added to the total volume delivered.
- The fast forward function can be used to remove any mechanical gap. If purging is not performed, a considerable delay may be incurred in the start of the infusion.

- Total volume cannot be cleared after the infusion starts without stopping the infusion.
- The volume under the fast forward function will not be calculated into the total volume.

## 6.5 Setting the Infusion Rate

- Tap the rate area on the touchscreen to enter the setting interface.




- Input the flow rate, and then tap [Confirm] to return to the infusion preparation screen.
- The flow rate varies with different syringe sizes. For details, see Table 6-2. Table 6-3 lists the relationship between the rate range and minimum increment.

Table 6-2 Relationship between syringe size and rate

| Syringe size (ml) | Setting range (ml/h) |
|---|---|
| 5 | 0.10-100.0 |
| 10 | 0.10-300.0 |
| 20 | 0.10-600.0 |
| 30 | 0.10-900.0 |
| 50/60 | 0.10-2000 |

Table 6-3Relationship between rate range and the minimum increment

| Rate range(ml/h) | Minimum increment(ml/h) |
|---|---|
| 0.10 - 99.99 | 0.01 |
| 100 - 999.9 | 0.1 |
| 1000 - 2000 | 1 |

⚠ CAUTION:

- When a syringe of a different size is installed and the flow rate is out of range, please reset the rate to its maximum valid rate.
- To change the flow rate in the infusion process, the infusion does not need to be stopped. After changing the infusion rate and confirming the change during infusion, subsequent infusion is performed at the rate after the change.

## 6.6 Puncture

Insert the vein infusion needle into the patient's vein.

## 6.7 Starting Infusion

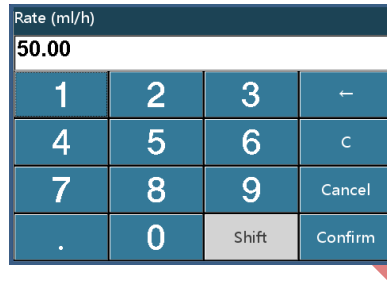
Tap the [Start] button to start infusion at the setting rate. The green indicator light illuminates.

⚠ CAUTION:

- Infusion can be started only when the prescribed values on the prescription are the same as the values set on the syringe pump.
- If no operation is performed after syringe installation for more than 2 minutes, the START-REMINDER alarm is generated.

## 6.8 Changing Rate During Infusion

- Tap the rate display area on the screen during infusion.




- After entering the rate and tapping [Confirm], the system returns to the original infusion interface and operates at the new rate; if you tap [Cancel], the system returns to the original infusion interface without change.

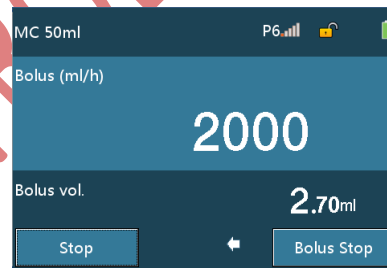
⚠ CAUTION:

- If no operation is performed on the reference or rate setting interface for more than 10 seconds, the system returns to the infusion interface automatically.

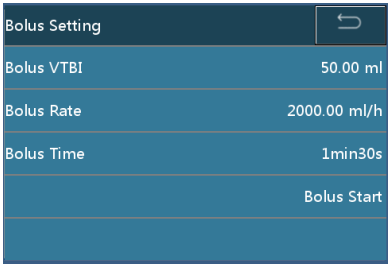
## 6.9 Bolus

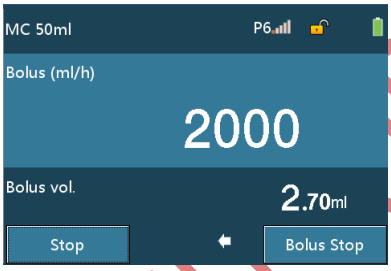
- Choose “Manual Bolus”, and set “Manual Bolus Limit”. During the infusion, tap [Bolus] for 1s to enter the bolus interface. Bolus will continue as long as the button is pressed and will stop immediately when the button is released. The pump automatically stops manual bolus when reaching the manual bolus limit even if the user keeps on holding the button.


- Choose “Rapid quantitative Bolus”, during the infusion, tap [Bolus] to enter the bolus VTBI interface, set the bolus volume, tap [Confirm] to start and tap [Bolus Stop] to stop the bolus and return to infusion interface.


- Choose “Automatic Bolus”, during infusion; tap [Bolus] to enter the bolus setting interface. Set any two of Bolus VTBI, Bolus rate and Bolus Time, tap [Bolus Start] to enter the bolus interface, tap [ Bolus Stop] to stop the bolus




Bolus rates are different depending on the syringe specification as follows.

Table 6-4 Relationship between syringe size and bolus rate

| Syringe size (ml) | Bolus rate (ml/h) | Minimum bolus volume(ml) | Maximum bolus volume(ml) |
|---|---|---|---|
| 5 | 0.10 ~ 100.0 | 0.1 | 0.10 ~ 5.00 |
| 10 | 0.10 ~ 300.0 | 0.1 | 0.10 ~ 10.00 |
| 20 | 0.10 ~ 600.0 | 0.1 | 0.10 ~ 20.00 |
| 30 | 0.10 ~ 900.0 | 0.1 | 0.10 ~ 30.00 |
| 50/60 | 0.10~ 2000 | 0.1 | 0.10 ~ 50.00 |

CAUTION:

- Current bolus volume is displayed when bolus is running.
- Bolus volume will be accumulated into the total volume.

## 6.10 Stopping Infusion

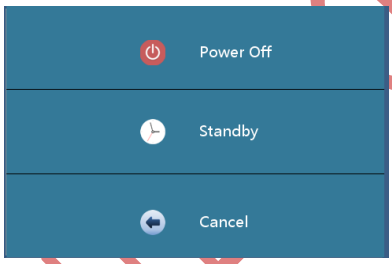
In the infusion process or after infusion, tap [Stop] to stop the operation.

### 6.11 Changing the Syringe

If the amount of solution in the syringe is getting low, repeat the steps in sections 6.3-6.6 to replace the syringe.

### 6.12 Powering Off the Pump

- Press the [ON/OFF] button, and tap [Power Off], [Standby] or [Cancel].




- Tap [Power Off] to shut down.
- Tap [Standby] to enter standby interface. The standby time can be modified.
- Tap [Cancel] to return to the previous interface.

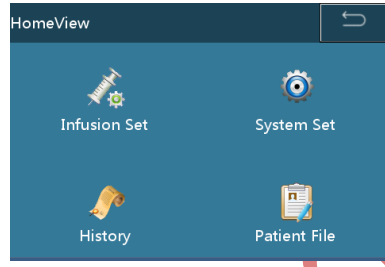
## 7 Setting the Syringe Pump

⚠ CAUTION:

- After the pump is powered off, all parameter settings will be automatically saved.
- Parts of parameters will not be saved if the device is forcibly shutdown.

### 7.1 Infusion Setting

Press the [HOME] button to enter the setting interface, tap [Infusion Set] to enter the detailed infusion setting interface. Infusion Mode, OCCL level, bolus mode, KVO rate, brand, relay set, micro mode, near finished and recent therapy can be set and adjusted here.

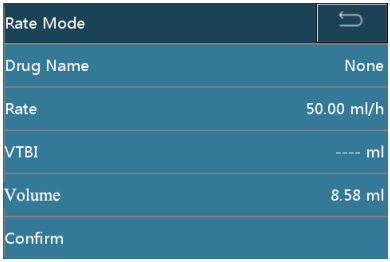




### 7.1.1 Infusion Mode

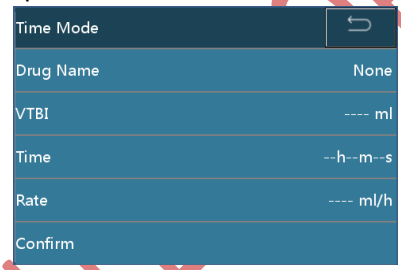
- Seven infusion modes are available: Rate, Time, Weight, Trapezia, Loading Dose, Sequence, and TIVA.
  - Rate mode

  In Rate Mode, set the drug name, rate, and VTBI and tap [Confirm] to operate.



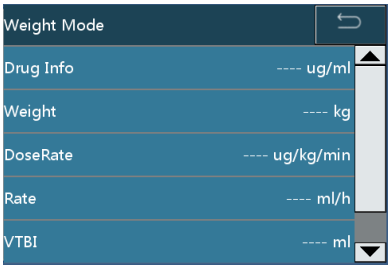

- Time mode

In time mode, set the drug name, VTBI, and Time and tap [Confirm] to operate.



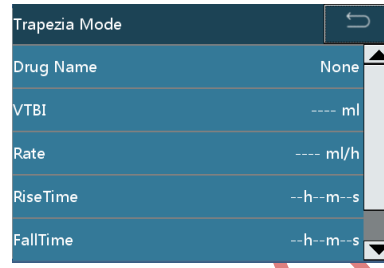

- Weight mode

In Weight mode, set the drug Info, Dose Rate, Weight, and VTBI, wait for the device to calculate the rate automatically, and then tap [Confirm] to operate.



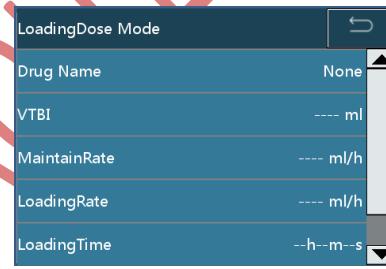

- Trapezia Mode

In Trapezia mode, set the drug name, VTBI, rate, rise time, and fall time, wait for automatic calculation of the rate, and then tap [Confirm] to operate.




- Loading Dose Mode

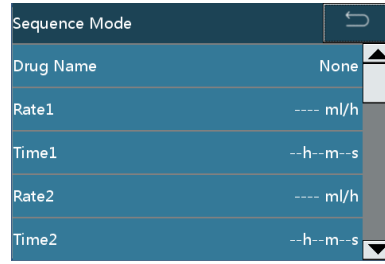
In Loading Dose mode, set the drug name, VTBI, maintain rate, loading rate, and loading time, wait for automatic calculation of the rate, and then tap [Confirm] to operate.




- Sequence Mode

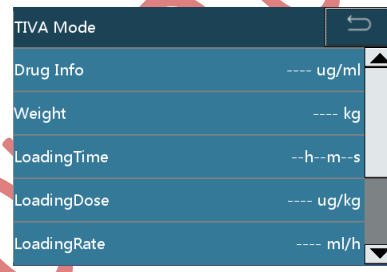
In Sequence Mode, set the drug name, 10 groups of sequence rate, and time and tap [Confirm] to operate in sequence.

Note: A sequence for which only the time is set but rate is not set is supported, which functions as a paused sequence of the infusion process.




- TIVA Mode

In TIVA mode, set the drug info, loading dose, loading time, dose rate, and weight, wait for automatic calculation of the rate, and then tap [Confirm] to operate.




### 7.1.2 Occlusion Level

Eleven occlusion levels are available (Factory setting is level 6).

Table 7-1 Relationship between occlusion level and pressure

| Occlusion level | Display | Pressure (mmHg) | Pressure (kPa) | Pressure (bar) | Pressure (psi) |
|---|---|---|---|---|---|
| 1 | P 1 | 225 | 30 | 0.3 | 4.35 |
| 2 | P 2 | 300 | 40 | 0.4 | 5.80 |
| 3 | P 3 | 375 | 50 | 0.5 | 7.25 |
| 4 | P 4 | 450 | 60 | 0.6 | 8.70 |
| 5 | P 5 | 525 | 70 | 0.7 | 10.15 |
| 6 | P 6 | 600 | 80 | 0.8 | 11.60 |
| 7 | P 7 | 675 | 90 | 0.9 | 13.05 |
| 8 | P 8 | 750 | 100 | 1.0 | 14.50 |

| | | | | | |
|---|---|---|---|---|---|
| 9 | P 9 | 825 | 110 | 1.1 | 15.95 |
| 10 | P 10 | 900 | 120 | 1.2 | 17.40 |
| 11 | P 11 | 975 | 130 | 1.3 | 18.85 |

⚠ CAUTION:

- When an occlusion alarm is generated, the motor automatically rotates inversely to release the pressure in the tube (Anti-Bolus function), so that no extra bolus will be infused during the operation of clearing the occlusion alarm.
- When you infuse viscous solutions with the Occlusion Level setting under 4 and the tubing is clear, occlusion alarm tends to be generated. Carefully observe the  symbol in the upper information area, and change the occlusion level if more than 2 bars are illuminated.
- When you operate the pump with the Occlusion Level setting over 8, the in-line pressure builds up substantially until Occlusion alarm is generated. Always make sure that the IV line is securely connected to the syringe.
- An occlusion alarm may be generated when high-viscosity liquid is infused at high rate through a thin intravenous needle. In this case, increase the occlusion level or decrease the infusion rate.

### 7.1.3 Bolus Mode

Three bolus modes are available: Manual Bolus, Rapid quantitative Bolus and Automatic Bolus. Please refer to chapter 6.9 for further instructions.

### 7.1.4 KVO

- KVO-rate can be adjusted from 0.1ml/h to 5ml/h (adjustment step: 0.01ml/h). The default rate is 1ml/h.
- Set the rate to 0.00 ml/h to disable the KVO function.

⚠ CAUTION:

KVO is initiated when the VTBI or infusion time is reached.

### 7.1.5 Brand

- You can choose the consumable brand in the following sequence: [Home]->[Infusion Set]->[Brand].
- Several brands of syringes of 5ml, 10ml, 20ml, 30ml, and 50/60ml have been preset and customized. Select the syringe accordingly for clinical use.

⚠ CAUTION:

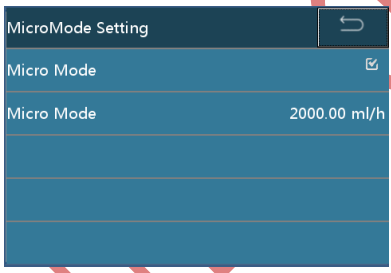
- Users must use the consumable brand which is specified by the manufacturer.
- To add in syringes of other brand, users are strongly recommended to contact the manufacturer or

manufacturer's representative to set and test, so as to ensure the infusion accuracy.

- This syringe pump supports at least 30 syringe brands, and each brand includes 5 different sizes of syringes.

### 7.1.6 Micro Mode Setting

After Micro Mode is selected, the maximum rate in Micro mode can be adjusted.




### 7.1.7 Near Finished

The Near Finished alarm is generated when infusion is almost completed. The duration from generation of this alarm to infusion completion can be adjusted from 1 min to 30 min (adjustment step: 1 min). By default, this alarm is generated 3 minutes before infusion completion.

### 7.1.8 Recent Therapy

The therapies of the recent 20 times are recorded. The recorded therapy can be started directly by simple selection.

## 7.2 System Set

### 7.2.1 Volume Set

Ten volume levels are available (the factory setting is level 5).


⚠ CAUTION:

- Do not set the alarm volume to a level lower than the ambient noise to ensure that alarms can be recognized correctly in time.
- The alarm system may fail when the alarm volume is set to an extreme value. Check alarm limit values based on clinical conditions.

### 7.2.2 Display Set

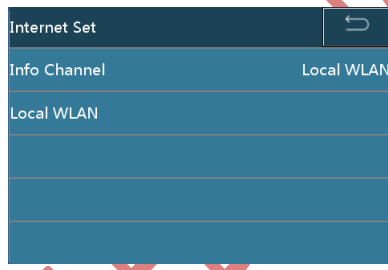
- Seven different color options are available for UI type.
- The brightness could be adjusted in [Normal Bright].
- All the parameters of the night mode could be adjusted here.

⚠ CAUTION:

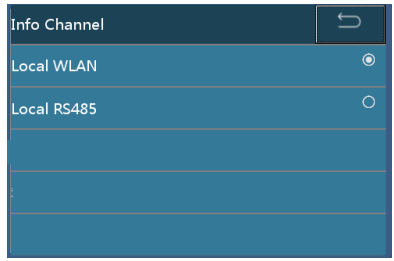
In night mode, the setting range of start time is 17:00-09:00, and the setting range of finish time is the same as that of start time. By default, the start time is 00:00 and finish time is 00:00.

### 7.2.3 Internet Set

- [Info Channel] and [Local WLAN] can be chosen and set.




- Tap [Info Channel] to choose the channel type.
  - Choose [Local WLAN] to use local WLAN channel to connect to the network, and the local WLAN parameters can be set.
  - Choose [Local RS485] to use local RS485-LAN cable to connect to the network.






⚠ CAUTION:

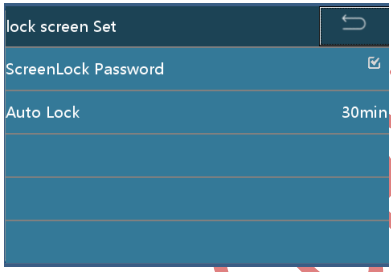
- The setting of [Local WLAN] and [Local RS485] must be done by the manufacturer's representatives. Please contact manufacturer or local distributer for further information.
- Only accessories or devices supplied or specified by the manufacturer are allowed to be connected to the pump. Otherwise, pump exception and other unpredictable hazards may be incurred.
- Tap [Local WLAN] to set the WLAN parameters.


- [WIFI Disable] must be deselected, the AP name of the network must be input, and the TCP/IP's information must be set.

### 7.2.4 Lock screen Set

- Tap [Screen Lock Password] to enable/disable the screen lock password function. When the function is enabled, a password is required to unlock the screen. When the function is disabled, no password is required to unlock the screen.
- Tap [Auto Lock] to set the screen auto lock function. This

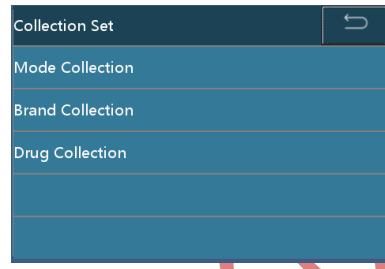
function could be set to: OFF, 15s, 30s, 1min, 2min, 5min, 10min, or 30min. The default value is OFF, indicating that the screen auto lock function is disabled.




### 7.2.5 Collection Set

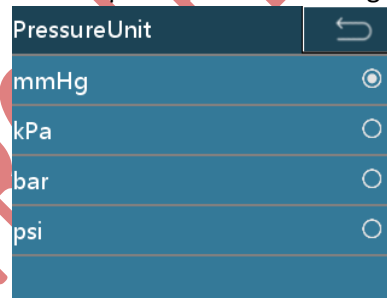
- [Mode Collection]: Choose the frequently used infusion mode from the [Infusion mode] option. Once the frequently used infusion modes are chosen, the unnecessary modes will not appear in the list of 7.1.1 [Infusion mode] option. The default setting is “all the seven infusion modes are chosen”, including Rate mode, Time mode, Weight mode, Trapezia mode, Loading Dose mode, Sequence mode and TIVA mode.
- [Brand Collection]: Choose the frequently used infusion set’s brand from the [Brand] option. Once the frequently used brands are chosen, the unnecessary brands will not appear in the list of 7.1.5 [Brand] option. The default setting is “all the preloaded brands are chosen”
- [Drug Collection]: Choose the frequently used drugs from the drug library. Once the frequently used drugs are

chosen, the chosen drugs will be shown on the top of the drug library list. The default setting is “none of the drug is chosen”. The data of the drug library is not edited by the manufacturer.



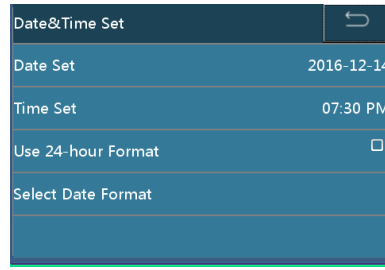

### 7.2.6 Pressure Unit

Choose the measurement unit for the pressure. The optional units are: mmHg, kPa, bar and psi. The default setting is mmHg.




### 7.2.7 Date & Time Set

Set the date, time, and their format.



### 7.2.8 Maintenance

- Tap [Maintenance] option to do the [Language Select], [Touch Adjust], [Factory Data Reset], [Local Set] and check the version information.
- To check the version information, follow the route of: [Home] -> [System Set] -> [Maintenance] -> [Version Info].

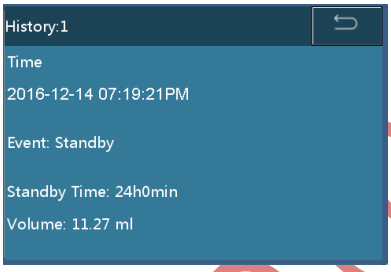
### 7.2.9 Alarm Set

- The parameters on [Alarm Set] include [Reminder Alarm], [Near Finished], and [Tube Off].
- [Reminder Alarm] provides two alarm levels: [Low] and [Middle]. The default level is [Low].
- [Near Finished] provides two alarm levels: [Low] and [Middle]. The default level is [Low].
- [Tube Off] provides two options: enable and disable. You can select this item to enable the Tube Off alarm.

⚠ **CAUTION:**

Alarm setting must be performed by professional technicians of the local distributor to ensure the alarm system priority of the device.

## 7.3 History


The history records are listed in Table 7-2.

Table 7-2 History records

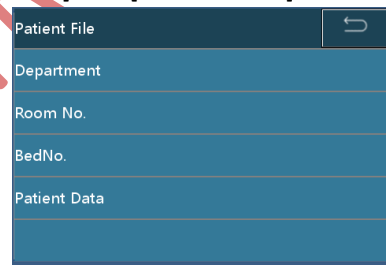
| **Event** | **Record Parameters** |
|---|---|
| Start up | Occurrence time |
| Shutdown | Occurrence time |
| Standby | Occurrence time, standby set time |
| Start | Occurrence time, rate, Volume |
| Bolus | Occurrence time, Bolus rate, Bolus way |
| Bolus stop | Occurrence time, Bolus rate, Bolus accumulated volume |
| Stop | Occurrence time, rate, accumulated volume |
| KVO | Occurrence time, accumulated volume, KVO rate |
| KVO stop | Occurrence time, KVO rate, KVO accumulated volume |
| Flow rate change | Occurrence time, Flow rate before and after change |
| Alarm | Occurrence time, alarm event, system trouble with trouble code |
| Purge | Occurrence time, purge rate, accumulated volume |
| Purge stop | Occurrence time, purge rate, purge accumulated volume |

⚠ CAUTION:

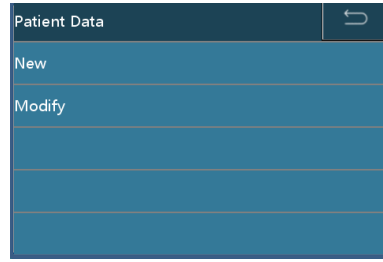
- When the syringe pump loses the power (both the mains supply and internal power supply), the alarm log will be auto saved in the memory and always saved no matter when the power is resumed. The system will auto load such alarm log upon power resumption.
- A maximum of 2000 history records can be saved. When the record number reaches the storage limit, the earliest record will be replaced by the new one.
- Alarm system can't be powered off separately by an operator unless the pump is powered off. The time of powering off is captured in the history records.

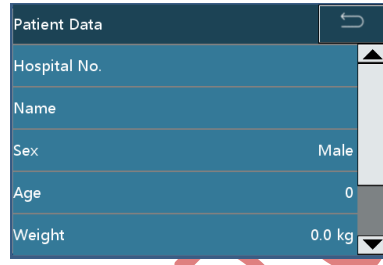
## 7.4 Patient File

- Tap [Patient File] to enter the patient file page. The [Department], [Room No.], [Bed No.] and [Patient Data] could be set up.




- Tap [Patient Data] option to enter patient data setting page. Choose [New] to build a new patient data and the previous patient data will be cleared automatically. Choose [Modify] to modify the current patient data.




## 7.5 Use Built-in Battery

- If no AC/DC power supply is available, the built-in battery powers the pump.
- When external power stops working, the built-in battery starts and the yellow indicator illuminates (low level alarm) with a short alarm sound.
- Before using the pump for the first time or using the pump after the pump is not used for a long time, please fully charge the battery.
- The approximate remaining power in the built-in battery is displayed by [battery] indicators. During battery operation, battery discharged is shown by a decreasing number of active indicators.
- When the syringe pump is connected to any external AC or DC power supply, the charging of the built-in battery starts

automatically. When a battery is charging, a lightning symbol will be displayed at the left side of the battery symbol on the screen.

⚠ CAUTION:

- If AC or DC power is connected, the battery will be recharged automatically.
- Use AC power to charge the battery. If recharged by an external 12 VDC power supply, the battery cannot be fully charged (50% at most).
- During infusion, when the pump is powered by the built-in battery, if a low-battery alarm occurs, tap [SILENCE] to silence the alarm. The alarm will repeat in two minutes, connect the pump to AC/DC power supply immediately. If battery empty alarm occurs, the silence does not function and syringe pump will stop.
- 3 minutes before the battery empty, the pump will automatically power off.
- The actual battery duration may be different and affected by the ambient temperature, flow rate, external communication, etc.
- If the battery is aging, the actual battery duration may be shorter. Periodically check the battery.
- The battery should be replaced with new one every two years to ensure the battery operation time.

## 7.6 Connecting to the Infusion Central Monitoring System (Optional)

Syringe pumps can be connected to the Infusion Central Monitoring System which can obtain performance data of all connected pumps remotely.

⚠ CAUTION:

Syringe pump cannot be operated through the Infusion Central Monitoring System.

### 7.7 Nurse Call (Optional)

After syringe pump is connected to the central monitoring system, patient can press nurse pager in bed, and then the central monitoring system in nurse station would give out a sound tip and display patient's information in the screen, so that the nurse is alerted to the patient's need in time.

### 7.8 Connect to LAN

Syringe pumps can be connected to the Infusion Central Monitoring System which can obtain performance data of all connected pumps remotely through theLAN communication module. Contact manufacturer or manufacturer's representatives for more details.

### 7.9 Drug Library

The syringe pump has a drug library that can store at least 2000 drug types. A user can select the desired drug type from the drug library directly.

## 8 Troubleshooting

### 8.1 Alarm

The syringe pump provides users with a variety of status information about itself and its injection process. If any abnormality is detected, the syringe pump generates an alarm and notifies users in the form of sound, light, and character.

All the alarms on this pump are of technical type.

Considering the importance of abnormal information, alarm information is classified into three levels from the viewpoint of security: low-level, mid-level, and high-level alarms. For audio and visual expressions of alarms at three levels, see Table 8-1. The alarm volume ranges from 45 dB to 80dB.

Table 8-1 Alarm severity and the audio and visual expressions of each level

| Alarm | Sound | Light |
|---|---|---|
| Low-level alarm | Give out three beeps at intervals of 25 seconds. | The yellow indicator is steady on. |
| Mid-level alarm | Give out three beeps at intervals of 15 seconds. | The yellow indicator is flashing. |
| High-level alarm | Give out a series of beeps at intervals of 15 seconds. | The red indicator is flashing. |

When an alarm (except Battery Empty) occurs, tap [SILENCE] to pause the alarm sound. But the buzzer beeps again if you do not eliminate the alarm within 2 minutes.

⚠ CAUTION:

The setting of the alarm will be saved when the power is cut. When the pump restarts from a power failure situation, the alarm setting will be reloaded to the system and remains the same as it was before the power failure.

 WARNING:

There will be a potential risk if the same or similar devices are using different alarm setting in any specialized region.

## 8.2 Faults and Troubleshooting

Table 8-2 Alarm symptom, alarm level, fault cause, and troubleshooting

| Alarm Symptoms | Alarm level | Causes | Troubleshooting |
|---|---|---|---|
| No Power Supply | Low-level | No external AC/DC power supply is connected. | Immediately connect the AC power supply or the external DC power supply. |
| No Battery | Low-level | The syringe pump has no built-in battery or the built-in battery operates abnormally. | Replace the built-in battery. |

| Alarm Symptoms | Alarm level | Causes | Troubleshooting |
|---|---|---|---|
| Low Battery | Low-level | The built-in battery is running critically low. | Immediately connect an AC power supply or an external DC power supply. |
| Battery Empty | High-level | The battery is completely empty. | Immediately connect an AC power supply or an external DC power supply. |
| Near Finished | Low-level | The infusion is reached the Near Finished Alarm setting period. | Wait until the infusion finishes. |
| Pressure Alarm | Low-level | The occlusion pressure is high. | Check the infusion tube, and remove the cause, continue to inject |

| Alarm Symptoms | Alarm level | Causes | Troubleshooting |
|---|---|---|---|
| OCCL | High-level | 1.The syringe IV line is occluded.<br>2.The OCCL level is too low for high viscosity drug's infusion. | Tap [Stop] to stop the injection. Check and remove the cause, continue to inject. |
| Syringe Near Empty | Low-level | It takes less than three minutes to complete the infusion. | Wait until syringe is completely empty |
| Syringe Empty | High-level | The syringe is empty. | Tap [Stop] to clear the alarm. |
| Syringe Unknown | High-level | Syringe disengagement from slit during infusion. | Tap [Stop] to clear the alarm. Check if the syringe pump clamp or syringe is installed correctly. |

| Alarm Symptoms | Alarm level | Causes | Troubleshooting |
|---|---|---|---|
| Syringe Install Error | High-level | The slider is loose during the infusion or the slider is not installed in a right way. | Tap [Stop] to clear the alarm. Check if the holder is installed correctly. |
| Finished | High-level | The limit amount or the infusion time is complete | Tap [Stop] to clear the alarm. |
| Reminder Alarm | Low-level | Forget to operate the alarm (no button operation is made two minutes after the syringe is installed). | Tap any button to clear the alarm. |

| Alarm Symptoms | Alarm level | Causes | Troubleshooting |
|---|---|---|---|
| Standby End | Low-level | Standby mode is ending | Tap cancel to exit Standby mode. |
| Tube off (only 30, 50/60 ml syringe) | Middle-level | The extension tube of the syringe falls off. | Check whether the tube falls off. If yes, reinstall it. If no, tap [Stop] to eliminate the alarm and continue the infusion. |



## 8.3 Errors and Troubleshooting

When the device is faulty, a corresponding error code appears on the interface and at high-level alarm is generated.

Table 8-3 Errors and troubleshooting

| Error code | Alarm level | Troubleshooting |
|---|---|---|
| Sensor Error | High-level | |
| Motor Error | High-level | |

| | | |
|---|---|---|
| Circuitry Error | High-level | Record the error code, power off the pump, and contact manufacturer or manufacturer's representatives. |
| Driver COM Error | High-level | |
| System Error | High-level | |

# 9 Maintenance

## 9.1 Cleaning and Disinfection

- Before cleaning the pump, be sure to turn off the power and disconnect the AC or DC power cables, disconnect the device from the patient.
- If any solution spills on the pump or the pump gets heavily soiled, wipe it with a wet soft cloth dampened with cold or lukewarm water.
- Use a piece of dry soft cloth to clean the AC power supply socket, USB socket or the nurse call socket, ensure that the socket is dry before using it.
- If the clamp or clutch needs to be removed for cleaning, contact your local distributor.
- Do not use organic solvent such as alcohol or thinner.
- If disinfection is necessary, use common disinfectors such as Chlorhexidinegluconate and Benzalkonium chloride. After using the agent with a soft cloth, wipe off it with a soft cloth dampened with water or warm water. When using the disinfecting agent, follow the caution of each agent.
- Do not autoclave the syringe pump.

- Never use a dryer or similar device to dry the syringe pump.
- If liquid spills onto the pump, check whether the pump still functions normally. Test the insulation and leakage current when necessary.
- Do not soak the syringe pump into water.

WARNING:

Do not clean or disinfect the pump when it is running.

## 9.2 Periodic Maintenance

Perform a periodic maintenance inspection to ensure safe operation and the longest possible life of the syringe pump, and check the syringe pump once every 2 years. You can maintain some items by yourself and contact your local distributor to maintain some other items. Contact manufacturer or manufacturer's representatives if any doubts remain.

### 9.2.1 Checking the Appearance

- Appearance checking: There are no cracks or damages.
- Button operations: If you can press the buttons smoothly, they are available.

### 9.2.2 Checking the Power Cable

- Check the appearance of the power cable. If the appearance is damaged and the plug and the socket are in poor contact, contact manufacturer or manufacturer's representatives for replacement in time.
- If you connect the syringe pump to the AC/DC power and there is no indication of powering on, contact

manufacturer or manufacturer's representatives for maintenance in time.

### 9.2.3 Checking the Infusion Rate

Check the infusion flow once every 2 years by using the graduate and stopwatch.

Checking condition:

| Syringe | Infusion rate | Infusion time | Volume in graduate |
|---|---|---|---|
| MC /B.Braun50/60ml | 60ml/h | 10min | 9.8-10.2ml |

### 9.2.4 Alarms

- Syringe Unknown

  Pull of the syringe clamp during infusion, alarm information will be visible on the display and audible.

- Syringe Install Error

  Press the clutch during infusion, alarm information will be visible on the display and audible.

- Occlusion

  Checking condition:

| Syringe | Infusion rate | Occlusion level | Alarm time |
|---|---|---|---|
| MC /B.Braun50/60ml | 25ml/h | 600mmHg | Within 3 minutes |

⚠ CAUTION:

The syringe pump will perform a power-on self-test for the alarm system once powered on. You can judge whether the alarm system

works properly as described below. If no, stop using the syringe pump and contact your distributor for repair soon.

### 9.2.5 Electric and Mechanical Safety

To ensure safety, test the insulation voltage, leakage current and earth resistance according to the IEC 60601-1.

### 9.2.6 Checking the Built-in Battery

- Perform the following inspections on the battery every half year, or after the pump is not used for a long time:
- Connect the syringe pump to the AC power supply to fully charge the battery.
- Turn on the power and install the syringe (50/60 ml syringe).
- Set the infusion rate to 5 ml/h and start the infusion. Record the start time.
- Operate the system until it stops infusing due to battery empty alarm.
    - If the continuous operation duration reaches 80% or more of the asserted battery operation time, the battery is in good condition.
    - If the continuous operation duration is shorter than half of the asserted battery operation time, the battery reaches the end of its service life. In this case, you must replace the battery. You are suggested to contact the local distributor for battery replacement.
    - Record how long can the operation last after a Low

Battery alarm and Battery Empty alarm are triggered respectively. If the operation lasts for less than 30min after a Low Battery alarm is triggered or lasts for less than 3min after a Battery Empty alarm is triggered, contact the local distributor for battery replacement.

- After the battery level check is completed, recharge the battery for next use.

⚠ CAUTION:

Due to the inherent characteristics of aging battery life, to ensure the safety of the use of syringe pumps, after built-in battery is used 2 years, please contact the manufacturer or manufacturer's representative to replace the battery.

### 9.2.7 Replacing the Battery

- Remove the built-in battery.
  - Turn the power off and disconnect the power cable.
  - Use a screwdriver to loosen the battery cover fixing screws between the front panel and real panel.
  - Disconnect the battery cable connector.
  - Remove the battery.
- Install the built-in battery.
  - Insert the new battery into the battery compartment.
  - Insert the connector of the battery cable into the battery
  - Use a screwdriver to tighten the screws between the front panel and real panel.

⚠ CAUTION:

Replace the battery if the syringe pump is not likely to be used, especially the battery operation time becomes shorter.

⚠ WARNING:

- The battery's replacement must be done by specialist who has been trained to perform such operations. The replacement of lithium batteries by inadequately trained personnel could result in an unacceptable risk hazard.
- Please strictly follow the instructions to replace the battery, and the battery should only be provided by the manufacturer. Using other batteries will result in a loss of warranty by the manufacturer as no safe operation can be guaranteed.
- Do not disassemble, short circuit or throw the battery into fire in case of the danger caused by linkage or explosion.
- Please follow local guidelines to dispose of the old battery.
- The battery shall be changed with new one every two years to assure the battery operation time.

## 9.3 Maintenance

- If any problems arise, explain the situation to the manufacturer or manufacturer's representative and request repair of the pump.
- Never disassemble or try to repair the syringe pump yourself. Doing so may cause a serious malfunction. The manufacturer and the distributor will not take any responsibility for any syringe pump

that has been disassembled, modified or used for any purpose other than that for which it is intended.

- If the syringe pump is dropped or subjected to (severe) impact, remove it from service even if it doesn't appear damaged externally. Request the manufacturer or manufacturer's representative to inspect it for any possible internal problem(s).
- When pump is intended used under the road ambulance environment, check the fixation system, maintain system before every use.

⚠ CAUTION:

Service engineers can request for the related service manual from the manufacturer if needed.

⚠ WARNING:

- The accessories' replacement must be done only by a trained service engineer who has been trained to complete such operations.
- The pump should not be serviced or maintained while in use with the patient.

## 9.4 Storage

- Avoid water spills.
- Never store in a hot and humid place.
- Store the pump away from excessive vibration, dust and corrosive gas.
- Store the pump out of direct sunlight as ultraviolet ray may result

in discoloration.

### 9.5 Transportation

The syringe pump can be transported by common vehicles but should be protected from being hit, shaken, or excessive moisture like direct exposure to rain and snow. Transportation method shall be selected in accordance with the contract specifications specified in the original order of the syringe pumps.

### 9.6 Environmental Protection and Recycling

At the end of the product's service life, please contact the distributor of the product for appropriate recycling. Alternatively, dispose of the product and its battery according to the local laws and regulations.

## 10 Flow Rate Characteristics

The following test is performed in accordance with the IEC60601-2-24:2012 standard. It is used to observe the infusion accuracy and the occlusion response. (For detailed test conditions, see the IEC60601-2-24:2012 standard.)

⚠ CAUTION:

- The infusion accuracy and the occlusion response may be affected by the use conditions including the pressure, temperature, humidity, IV set, and infusion tube.
- The infusion accuracy does not reflect the clinical standards, for example, patients' age and weight and medicine taken.

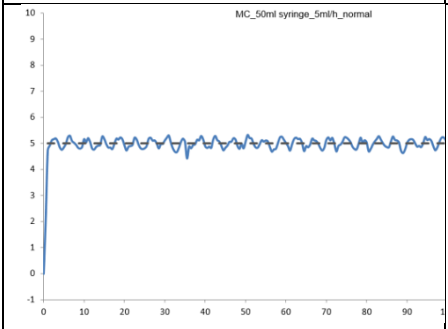
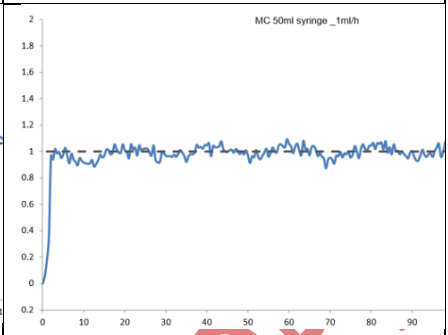
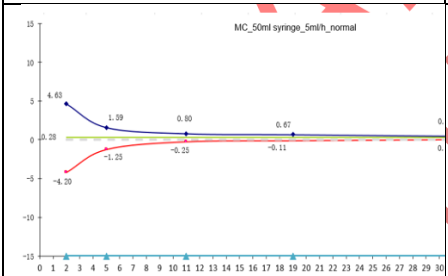
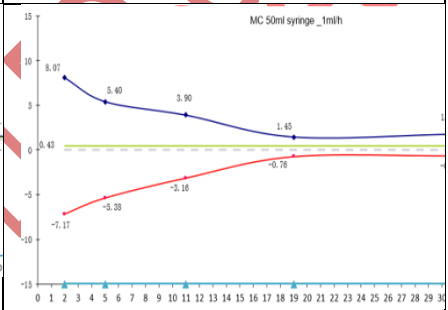
- The experiment data only represents the measurement data in the lab.
- The maximum volume of liquid that might be infused by the syringe pump in a single fault condition must not exceed 5ml.

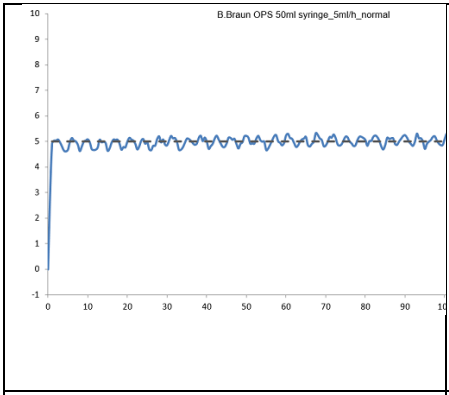
### 10.1 Flow Rate Characteristics

Start-up and Trumpet curves show the characteristics of the syringe pump after the injection begins and the injection changing status after the syringe pump reaches a normal flow rate.

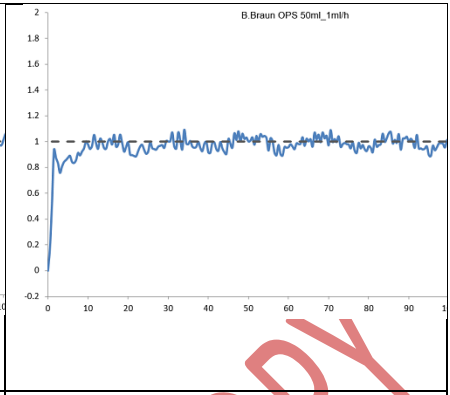
The following test method is performed in accordance with the method mentioned in chapter 201.12.1.102 of the standard IEC 60601-2-24:2012.

- Accuracy test conditions:
  - Temperature: 21°C;
  - Relative humidity:60%;
  - Syringe type: MC (5ml, 10ml, 20ml, 30ml, 50/60ml), B.Braun (20ml, 50/60ml); 4 sets each.
  - Syringe pump: 1 set
  - Sampling interval: 0.5min
  - Test Period: 120min

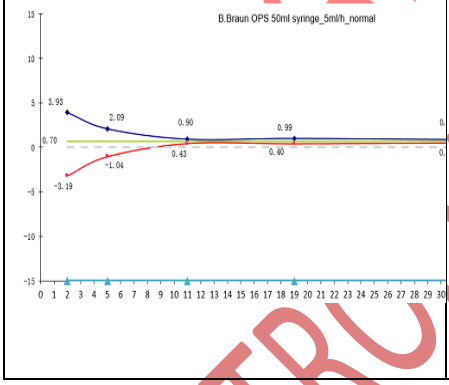
| Start-up curves of MC(50/60ml) 5ml/h | Start-up curves of MC(50/60ml) 1ml/h |
| --- | --- |
|   |   |
| Trumpet curve of MC(50/60ml) 5ml/h | Trumpet curve of MC(50/60ml) 1ml/h |
|   |   |
| Start-up curves of B.Braun(50/60ml) 5ml/h | Start-up curves of B.Braun(50/60ml) 1ml/h |

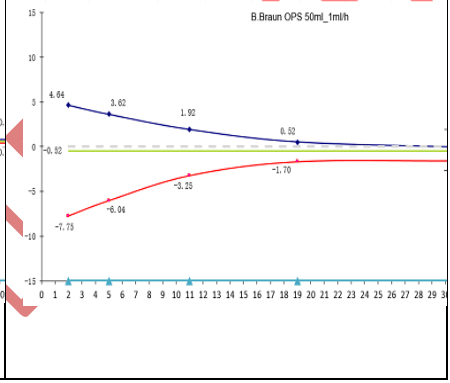



Trumpet curve of B.Braun(50/60ml) 5ml/h




Trumpet curve of B.Braun(50/60ml) 1ml/h






## 10.2 Occlusion Characteristics

The occlusion characteristics are described with the longest response time of occlusion alarm and its related bolus volume.

The following test method is accordance with the method mentioned in chapter 201.12.4.4.104 of the standard IEC 60601-2-24:2012.

- Occlusion test conditions:
  - Temperature: 21°C;
  - Relative humidity: 65%;
  - Syringe type: MC (50/60ml); 1 set

- Length of the infusion tube: 1m

Table10-1The occlusion level, alarm delay time and pill amount under the rate of 5ml/h

| Infusion rate | Occlusion pressure level | Occlusion pressure (mmHg) | Occlusion alarm time (hh:mm:ss) | Bolus (ml) |
|---|---|---|---|---|
| 5ml/h | P1 | 225±145 | 00:09:30 | 0.08 |
| | P11 | 975±145 | 00:17:28 | 0.63 |

Table 10-2The occlusion level and alarm delay time under the rate of 1ml/h

| Infusion rate | Occlusion pressure level | Occlusion pressure (mmHg) | Occlusion alarm time (hh:mm:ss) |
|---|---|---|---|
| 1ml/h | P1 | 225±145 | 01:00:05 |
| | P11 | 975±145 | 02:01:38 |

Table10-3The occlusion level and alarm delay time under the rate of 0.1ml/h

| Infusion rate | Occlusion pressure level | Occlusion pressure (mmHg) | Occlusion alarm time (hh:mm:ss) |
|---|---|---|---|
| 0.1ml/h | P1 | 225±145 | 08:24:20 |
| | P11 | 975±145 | 22:44:13 |

⚠ CAUTION:

Unit conversion list

| Description | Unit | Unit conversion |
|---|---|---|
| Pressure | kPa | 1kPa=7.5mmHg |

| | | |
|---|---|---|
| | psi | 1psi=51.724mmHg |
| | bar | 1bar=750mmHg |

Appendix A Electromagnetic Compatibility (EMC)

The MSP-01syringe pump conforms to EMC standard IEC 60601-1-2:2014.



| Guidance and manufacturer's declaration – electromagnetic emissions | | |
|---|---|---|
| The MSP-01 syringe pump should be used under the regulation electromagnet environment. The user should operate the MSP-01 syringe pump under following electromagnet environment. | | |
| Emission measurement | conformance | Electromagnet environment-instructions |
| Radio-frequency emission CISPR 11 | Group 1 | MSP-01 syringe pump only use radio-frequency while operating its internal functions, therefore, the radio-frequency is much low and has little interference to the electronic devices nearby. |
| Radio-frequency emission CISPR 11 | Class A | The MSP-01 syringe pump can be used in any building including civil residence. |
| Harmonic emission IEC61000-3-2 | Class A | |
| Voltage fluctuation and flashing IEC 61000-3-3 | conform | |

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| The [MSP-01] is intended for use in the electromagnetic environment specified below. The customer or the user of the [MSP-01] should assure that it is used in such an environment. | | | |
| IMMUNITY test | IEC60601test level | Compliance level | Electromagnetic environment –guidance |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±8 kV contact discharge<br>±15 kV air discharge | ±8 kV contact discharge<br>±15 kV air discharge | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient(EFT) IEC61000-4-4 | ±2 kV power cable<br>±1 kV I/O cable | ±2 kV power cable | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ±1 kV difference mode<br>±2 kV common mode | ±1 kV difference mode<br>±2 kV common mode | |
| The voltage dropping, short interruption and voltage change IEC 61000-4-11 | 0% 0.5 cycle At 0º, 45 º, 90 º, 135 º, 180 º, 225 º, 270 º and 315 º;<br>0% 1 cycle And 70% 25/30 cycles Single phase: at 0 º<br>0% 300 cycle | 0% 0.5 cycle At 0º, 45 º, 90 º, 135 º, 180 º, 225 º, 270 º and 315 º;<br>0% 1 cycle And 70% 25/30 cycles Single phase: at 0º<br>0% 300 cycle | Mains power quality should be that of a typical commercial or hospital environment. If the user of the[MSP-01] requires continued operation during power mains interruptions, it is recommended that the [MSP-01] be powered from an uninterruptible power supply or a battery. |

| | | | |
|---|---|---|---|
| Power frequency magnetic fields (50/60Hz) IEC 61000-4-8 | 30A/m | 30A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment |
| NOTE $U_T$ is the AC mains voltage prior to application of the test level. | | | |

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| The [MSP-01] is intended for use in the electromagnetic environment specified below. The customer or the user of the [MSP-01] should assure that it is used in such an environment. | | | |
| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic environment – guidance |
| Conducted RF IEC61000-4-6 | 3 Vrms<br>150 kHz to 80MHz;<br>6 Vrms in ISM bands Between 0.15MHz and 80 MHz;<br>80% AM at 1 kHz | 3 Vrms<br>150 kHz to 80MHz;<br>6 Vrms in ISM bands Between 0.15MHz and 80 MHz;<br>80% AM at 1 kHz | Portable and mobile RF communications equipment should be used no closer to any part of the [MSP-01], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>Recommended separation distance:<br>$d = 1.2\sqrt{P}$<br>$d = 1.2\sqrt{P}$<br>80M~800MHz |
| | | | |
| | | | |
| Radiated RF IEC61000-4-3 | 3 V/m<br>80 MHz – 2.7 GHz;<br>27V/m:380-390MHz; | 3 V/m<br>80 MHz – 2.7 GHz;<br>27V/m:380-390MHz; | |

| | | | |
|---|---|---|---|
| | 28V/m:430-470MHz;<br>9V/m:704-787MHz;<br>28V/m:800-960MHz;<br>28V/m:1700-1990MHz;<br>28V/m:2400-2570MHz;<br>9V/m:5100-5800MHz; | 28V/m:430-470MHz;<br>9V/m:704-787MHz;<br>28V/m:800-960MHz;<br>28V/m:1700-1990MHz;<br>28V/m:2400-2570MHz;<br>9V/m:5100-5800MHz; | $d = 2.3\sqrt{P}$<br>800M~2.5GHz<br>where Pis the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and dis the recommended separation distance in metres (m).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a],should be less than the compliance level in each frequency range[b].<br>Interference may occur in the vicinity of equipment marked with the<br>  <br>following symbol: |
| NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.<br>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |

[a]Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment dueto fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the [MSP-01] is used exceeds the applicable RF compliance level above, the [MSP-01] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [MSP-01].

[b]Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [3] V/m.

Recommended separation distances between portable and mobile RF communications equipment and the [MSP-01]

The [MSP-01] is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the [MSP-01] can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the [MSP-01] as recommended below, according to the maximum output power of the communications equipment.

| Rated maximum output power of transmitter (W) | Separation distance according to frequency of transmitter(m). | | |
|---|---|---|---|
| | 150k~80MHz $d = 1.2\sqrt{P}$ | 80M~800MHz $d = 1.2\sqrt{P}$ | 800M~2.5GHz $d = 2.3\sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the recommended separation distanced in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where

| |
|---|
| Pis the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.<br>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.<br>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. |

## Appendix B Default Factory Settings

This chapter lists some default factory settings of syringe pump. Users can not modify the default factory settings, but if necessary, they can recover the syringe pump to the default factory settings state.

Parameters

| Parameters setting | The default factory setting |
|---|---|
| KVO flow rate | 1ml/h |
| Pressure unit | mmHg |
| Occlusion pressure | P6 600mmHg |
| Near end | 3min |
| Built-in consumable brand | MC(5,10, 20, 30, 50/60ml),<br>B.Braun OPS(20,50/60ml) |

System time

| System time and date | The default factory setting |
|---|---|
| Time | 00:00 |
| Date | 2014-1-1 |
| Time form | 24 hours |

| | |
|---|---|
| Date form | Year-month-day |

Appendix C Parameter Units

| Parameter Name | Unit |
|---|---|
| Acti Agent | ng, ug, mg, g, U, KU, IU, EU, mmol, mol, kcal, mIU, kIU, and mEq |
| Conc. | ng/ml, ug/ml, mg/ml, g/ml, U/ml, KU/ml, IU/ml, EU/ml, mmol/ml, mol/ml, kcal/ml, mIU/ml, kIU/ml, and mEq/ml |
| DoseRate | x/min, x/kg/min, x/h, x/kg/h (x is ng, ug, mg, g, U, KU, IU, EU, mmol, mol, kcal, mIU, kIU, or mEq.) |
| LoadingDose | ng/kg, ug/kg, mg/kg, g/kg, U/kg, KU/kg, IU/kg, EU/kg, mmol/kg, mol/kg, kcal/kg, mIU/kg, kIU/kg, and mEq/kg |

# MEDICAL SYRINGE PUMP

# MSP-01



MANUAL BOOK

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